1076-201 Relative Incidence of Thrombus Formation on the CardioSEAL and Amplatzer Interatrial Closure Devices

Hitoshi Anzai, Vicki K. Chan, Jonathan M. Tobis, Barbara Natterson, Janine Krivokapich, Michael C. Fishbein, John S. Child, University of California, Los Angeles, Los Angeles, CA

Background: Transcatheter closure for atrial septal defect (ASD) and patent foramen ovale (PFO) is a promising alternative to surgical closure or anticoagulant therapy. A potential complication is thrombus formation on the device after implantation. This study compared the incidence of thrombus formation at one month post implant between the two FDA approved devices.
Methods: From February 2001 through August 2003, 68 patients (50 PFO, 13 ASD and 5 fenestrated septum) were treated successfully with the Amplatzer device (19 septal and 18 PFO occluders) or the CardioSEAL device (30). Antiplatelet medication (aspirin and clopidogrel) was prescribed for 6 months after the procedure. Fifty-two patients had transesophageal echocardiography (TEE) one month after device implantation (26±9 days).
Results: No patient suffered a thromboembolic episode during the 30 month follow-up period. TEE revealed that thrombus formation occurred more frequently on the CardioSEAL device (5/23, 22%) than on the Amplatzer device (0/27, 0%) (p=0.02). The presence of thrombus on the device in the follow-up period was defined as a new hypoechogenic nonplanar, partially mobile structure. Although thrombus disappeared or diminished following additional warfarin therapy in 3 patients, one patient had surgical explantation of the device due to progressive increase in the size of thrombus with hypermobility despite additional therapy with warfarin and argatroban.
Conclusion: The CardioSEAL device is more likely to have thrombus formation one month after insertion than the Amplatzer device. Most patients with thrombus on the device had a benign clinical course due to thrombus resolution following anticoagulation therapy. However, the high incidence of thrombus post implantation could explain the presence of recurrent embolic events observed in prior clinical trials.

1076-202 Impact of Aortic Stenting on Blood Pressure in Adult Coarctation

Sylvia S. Chen, Ann E. Donald, Clare Storry, Natalie Lloyd, Amanda Deighan, Marietta Charakida, Saemus Cullen, Philipp Bonhoeffer, Julian Halcox, John E. Deanfield, Heart Hospital, London, United Kingdom, Institute of Child Health, London, United Kingdom

Background: In patients with coarctation (CoA), persistent hypertension is the major cause of late morbidity and mortality. The relationships between obstruction, and more widespread vascular abnormalities as well as their potential for recovery are unknown.
Methods: We measured blood pressure (BP) over 24-hours, during exercise, and brachial-ankle systolic BP gradient in 11 patients (5 M, 6 F) pre- and 2-4 weeks post-stenting of CoA. Endothelium-dependent flow-mediated dilatation (FMD), and endothelium-independent dilation with nitroglycerine (GTN) were measured in the right brachial artery using high-resolution ultrasound in patients and in 12 controls. Carotid-radial pulse-wave velocity (PWV, arterial stiffness) was recorded.
Results: Prior to stenting, patients were hypertensive at rest and during exercise. Peak CoA gradient after stenting was significantly reduced (32.3±18.3 pre, versus 10.9±10.9mmHg post, P=0.001). Brachial-ankle systolic BP gradient was reduced after stenting (25.7±17.9 pre, versus 2.0±12.4mmHg post, p=0.02). Ambulatory BP (152±21 / 79±15 pre, versus 147±15 / 80±9mmHg post, p>0.7), mean pulse pressure (70±10 pre versus 66±13mmHg post, p=0.6), and systolic BP at peak exercise (227±24 pre versus 225±21mmHg post, p=0.7) were unchanged. Baseline FMD was significantly impaired compared with controls (4.2±0.6 versus 8.0±2.2% respectively, p=0.02) but unchanged post-stent (4.4±3.1%, p=0.9). Response to GTN (7.3±2.2 pre versus 8.2±4.8% post, p=0.7) and PWV (8.3±1.0 pre versus 8.4±1.2m/s post, p=0.4) were also unchanged.
Conclusion: Relief of the gradient in CoA does not result in an early change in blood pressure. Persistently abnormal vascular function and stiffness are likely to contribute. Long-term consequences on vascular remodelling and BP require study.

1076-203 Comparison of Surgical Repair With Balloon Angioplasty for Native Coarctation in Patients From Three Months to 16 Years of Age

Ronald J. Walhout, Jaco C. Lekkerkerker, Gordon H. Oron, Ger B.W.E Bennink, Erik J. Meijboom, University Hospital of Vaud, Lausanne, Switzerland, UMC Utrecht, Utrecht, The Netherlands

Objective
Surgery and balloon angioplasty for coarctation of the aorta have shown comparable short-term results, but long-term follow-up remains unclear. Comparison of surgical repair and balloon coarctation for native coarctation with a discrete localization is performed retrospectively.To allow a valid comparison between both techniques, identical inclusion criteria were applied.
Methods
Results of surgery (group A, 18 patients, age 0.30-14 years, median 0.63 years) and balloon angioplasty (group B, 28 patients, age 0.25-15 years, median 5.8 years) for isolated, native coarctation in children > 3 months, performed in a 10-year-period, were compared. Kaplan-Meier analysis was performed in both groups. Mean follow-up ranged from 2.5 to 11 years (mean 7.2 ± 2.4 years) in group A and from 1.4 to 10 years (mean 5.4 ± 2.8 years) in group B.
Results
Immediate success was obtained in all patients following surgery and 27/28 patients (96%) following balloon angioplasty. No statistical difference between surgery and angioplasty with respect to resultant pressure gradient decreases were found. Mortality was not encountered., Hospital stay varied from 6 to 20 days in group A and was 48 hours for all patients in group B. Recoarctation occurred in 1 patient (5.6%) in group A and in 2 patients (7%) in group B. Log-rank test reveals no statistical difference in freedom from reintervention probabilities between surgery and angioplasty. Aneurysm formation was not encountered.
Conclusions
Surgical repair and balloon angioplasty for native coarctation yield comparable reintervention probabilities in comparable patients. Aneurysm formation was not encountered following different treatment types.

1076-204 Transcatheter Patch Occlusion of Perimembranous Ventricular Septal Defects in Surgical Candidates

Eleftherios B. Sideris, Benjamin Macuil, Victor Varvarenko, Savvas Toumanides, Athenian Institute of Pediatric Cardiology, Athens, Greece, University of Texas, Houston, TX

Background: Perimembranous ventricular septal defect(VSD)is a challenging lesion because of its proximity to critical structures(aortic valve, tricuspid valve). Non-restrictive VSDs including mal-alignment ones are managed predominently by Surgery. The transcatheter patch(TP) is a balloon inflatable device requiring 24-48 hour support, before release. It is wireless and requires minimal subaortic rim; it could be therefore applicable for the above VSDs.
Methods: Sixteen consecutive surgical candidates for VSD correction were brought to the cath-lab for TP occlusion. There were 3 cases of non-restrictive VSDs including 2 malalignment ones(Fallot-Tetralogy).
All cases except for the Fallot Tetralogy cases which were cyanotic had large L-R shunts(Qp:Qs>2:1). Patient age varied between 2-35 years (med.7) and VSD size between 5-20 mm (med.12). They were occluded by 8 single and 8 double balloon/patches (15 nylon, 1 latex balloon). All VSDs were corrected through the femoral vein; four were crossed antegrade and 12 retrograde.
Results: All VSDs with the exception of 2 were successfully occluded (12 full occlusions, 2 trivial shunts). On follow-up (up to 3 years) there were no embolizations, aortic insufficiency(AI) or other late complications. In one case with aortic cusp prolapse and balloon related AI the patch was electively withdrawn. However, in a subsequent similar case, the balloon/patch was left in place despite the AI; upon patch release there was full occlusion and no AI. A 20 mm VSD was occluded by a large double latex balloon/patch; the balloon was ruptured the first 24 hours and was retracted. There was a case of ventricular fibrillation on implantation, which required acute cardioversion; however there was excellent final result, with full occlusion and no AI.
Conclusions: TP occlusion of VSDs in surgical candidates is effective and relatively safe. Expansion of the method to the infant VSD group could challenge the current surgical standard of treatment.

1076-205 Use of Amplatzer Duct Occluder for Complex Congenital Cardiac Lesions: Results From the US Registry Group

Zahid Amin, Ziyad M. Hijazi, Chen Chan, Makram Ebeid, Wolfgang Radtke, Frank Ing, Satinder Sandhu, Thomas Zellars, University of Nebraska, Omaha, NE

Background: The Amplatzer Duct occluder (ADO) is suitable for several complex congenital cardiac lesions. The ADO registry group was established for patients (pts) who received the device for complex lesions other than patent ductus arteriosus (PDA). We reviewed the registry pts to assess the efficacy of ADO. ***Methods:*** The pts were divided into two groups: pts with complex lesions (e.g., pulmonary arteriovenous malformation, coronary artery fistulas, veno-venous collaterals, etc.), and pts with severe medical condition (pts who needed surgery, but the risk of surgery was unacceptable) as paravalvular leaks, large PDA in pts with associated cardiac lesions (Table). ***Results:*** The overall success rate was 83%. Of the 42 pts with complex disease (mean weight 32 kg, range 3.5-92 kg), device placement was attempted in 34 with successful placement in all pts. Complete closure at six months follow up was 100%. One device embolized without any sequelae. In the severe medical condition (mean weight 16 kg, range 3.0-79 kg), placement was successful in 87% of pts in whom device placement was attempted. Complete closure rate at the last follow up was 94%. Two pts required surgery because of residual defects. There were 3 deaths in this group, none were related to the device or the procedure. ***Conclusions:*** The ADO appears to be an ideal device for complex congenital cardiac lesions with success rate of 100%. It can also be used as a therapeutic or bail out procedure in pts who are high risk candidates for surgery . **Registry Distribution**

Diagnosis	# of pts	Placement Attempted	Placement NOT Attempted	Success Rate
Coronary artery Fistula	12	6	6	100%
Pulmonary AVM	9	9	0	100%
Aorto-pulmonary collateral	3	2	1	100%
Veno-venous collateral	8	7	1	100%
Extracardiac Fenestration	4	4	0	100%
Blalock-Taussig Shunt	6	6	0	100%
Severe Medical Conditions	35	30	5	86%
Total	77	64	13	83%